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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,771	07/13/2001	Bettina Moeckel	203975US0X	1468

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/903,771

Applicant(s)

MOECKEL ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Application Status*

1. Claims 1-39 are pending in the instant application.

### *Restriction*

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-19 and 37-38, drawn to polynucleotides encoding a luxR transcriptional activation gene, vectors, host cells, and methods of making a luxR protein, classified in class 435, subclass 69.1.
  - II. Claims 20-21, drawn to *Corynebacterium* with an attenuated luxR gene, classified in class 435, subclass 252.32.
  - III. Claim 22, drawn to *E. coli* with a plasmid containing an attenuated luxR gene, classified in class 435, subclass 252.33.
  - IV. Claims 23-30, drawn to methods for making amino acids, classified in class 435, subclass 106.
  - V. Claims 31-36, drawn to hybridization methods, classified in class 435, subclass 6.
  - VI. Claim 39, drawn to a luxR protein, classified in class 530, subclass 350.
3. The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of Group I are related to the host cells of Groups II and III by virtue of their relation to luxR peptides. However, these polynucleotides and host cells are distinct by

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virtue of their different structures and functions. The polynucleotides of Group I are drawn to a *functional* luxR peptides while the host cells of Groups II and III contain genes encoding *attenuated* luxR peptides whose structure has been altered (reduced) relative to the functional gene and whose function is wholly distinct since the gene no longer functions to produce a fully active luxR peptide. Thus, these polynucleotides and host cells, as defined by their structures and functions, is patentably distinct from the others. Moreover, a search of these Groups together would be undue considering not only the distinct structure search that would not be co-extensive, but also the distinct textual search in the non-patent literature which search would include the same peptide name but a wholly distinct enzymatic activity. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups I and IV are related by virtue of luxR genes, claimed in Group I and attenuated in the methods of Group IV. These groups are distinct, however, because full-length, functional luxR genes are neither made nor used in the claimed methods. Thus, Groups I and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. §

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806.05(h)). In the instant case, the luxR genes can be used in a materially distinct process, such as in the recombinant production of the encoded protein. Thus, Groups I and V are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Group I is related to the peptides of Group VI by virtue of the fact that the DNA encode the peptides. The DNA molecule has utility for the recombinant production of the peptides in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because the peptide product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of peptides, such as nucleic acid hybridization assays. Therefore, Groups I and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups II and III are both drawn to bacteria containing an attenuated luxR gene. The Group are distinct because in Group II, the attenuated gene and be endogenous or exogenous while in Group III, a specific product is claimed. Moreover, the distinct bacteria have distinct structures and functions that differentiate the products. Thus, Groups II and III are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Groups II and III are related to Group IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the host cells can be used for a variety of different methods, such as in the recombinant production of luxR peptides (fragments). Thus, Groups II, III, and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The attenuated gene in the host cell of Groups II and III is related to Groups V and VI by virtue of the corresponding full-length, functional gene which encodes luxR. However, in the methods of Group V, the full length, functional gene is used, not the attenuated form; and in the proteins of Group VI, the related gene is the full-length functional form. Thus, Groups II and III are patentably distinct from Groups V and VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups IV and V are related by virtue of the luxR genes. However, each group of methods use distinct reagents and method steps to produce distinct products. Thus, Groups IV and V are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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The methods of Group IV are related to the proteins of Group VI by virtue of the unattenuated luxR gene. However, the gene used in the methods is wholly distinct from the gene that encodes the protein. Moreover, the proteins are neither used nor produced in the methods. Thus, Groups IV and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Group V are related to the proteins of Group VI because the genes used in the methods encode the protein of Group VI. However, the proteins are neither reagents nor products of the claimed methods. Thus, Groups V and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

#### *Election*

4. A telephone call was made to Daniel Pereira on September 3, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

***Conclusion***

5. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

September 18, 2002

